Remarks

Claims 1, 2, 4-9, 11, 12 and 14-16, 17-19 are currently pending in the application. Applicant gratefully acknowledges the Office Action's indication that claims 1, 2, 4-9, 11, 12, and 14-16 are allowable. Applicant also gratefully acknowledges the withdrawal of all previous rejections and objections.

Priority

The Office Action accorded an effective priority date of January 12, 2000 to claims 1, 2, 4-9, 11, 12 and 14-16. The Office Action, however, accorded an effective priority date of January 12, 2001, the filing date of the present application, to claims 17-19. Applicant does not acquiesce to this priority date determination for these claims or the Office Action's reasoning supporting this priority date determination. However, because the Office Action did not cite to any intervening art that would affect the patentability of the claims 17-19, resolution of the priority date dispute is not required for allowance of these claims. Therefore, Applicant respectfully requests the Office to pass this application to issue.

Discussion of the 35 U.S.C. § 112 Rejection

Claims 17-19 stand rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Office Action concedes that the originally filed disclosure recites the detection of p21, p16, and p27 in the alternative. The Office Action also concedes that the originally filed disclosure supports the detection of SA-beta Gal and p21, citing Example 5. However, the Office Action alleges that one skilled in the art would reasonable conclude that

Applicant was not in possession of claims 17-19 because the claims are drawn to the detection of both p27 and p16. Applicants respectfully traverses this rejection.

The fundamental factual inquiry to determine whether a newly added claim complies with the written description requirement is "whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." M.P.E.P. § 2163(I)(B). Contrary to the Office Action's assertions, one skilled in the art at the time the application was filed would have understood that the inventors were in possession of the detection of both p27 and p16 in the first and second samples. The Office Action does not question whether the Applicant was in possession of the detection of p27 or p16 individually, and in fact, the Office Action explicitly acknowledges this fact. Moreover, the Office Action does not question whether the Applicant was in possession of the detection of two biomarkers, because the Office Action explicitly acknowledged this, highlighting Example 5 and the biomarkers SA-beta Gal and p21. Nevertheless, the Office Action alleges, without any explanation or support, that one skilled in the art would not have understood that the Applicant was in possession of the ability to detect both the p27 and p16 biomarkers.

Contrary to the Examiner's assertion, however, the specification does provide support for the detection of p27 and p16. There is no *in haec verba* requirement – the added claim limitations can be supported in the specification though implicit or inherent disclosure. M.P.E.P. § 2163(I)(B). Nevertheless, the detection of p27 and p16 are supported by express disclosure in the application. For example, on page 5, lines 11-14, in the Summary of the Invention, the specification describes the detection of biomarkers in the plural:

> [t]he invention specifically provides methods for assessing efficacy of chemotherapeutic and chemopreventative agents in a human in need of treatment with such ***agents*** by detecting expression levels of ***biological markers*** associated with senescence, apoptosis or terminal differentiation. In the inventive methods, the amount of ***one or a plurality of senescence, apoptosis or terminal differentiation markers*** is quantitated in tissue and cell samples removed from an individual before and after exposure to the chemotherapeutic or chemopreventative agent."

(emphasis added). Further, in the Detailed Description of the Preferred Embodiments, the Applicant described one embodiment of her invention as:

> response to a chemotherapeutic or chemopreventive agent in an individual is determined by collecting a first tissue or cell sample from the individual before exposing the individual to the chemotherapeutic or chemopreventive agent, collecting a second tissue or cell sample from the individual after exposing the individual to the chemotherapeutic or chemopreventive agent, immunohistochemically staining the first and second tissue or cell samples using a detectably-labeled antibody directed against a biological marker associated with senescence, apoptosis or terminal differentiation, ***determining amount of expression of one or a plurality of biological makers associated with senescence, apoptosis or terminal differentiation*** in the first and second tissue or cell samples, and determining whether expression of the biological maker(s) associated with senescence, apoptosis or terminal differentiation was increased following exposure to the chemotherapeutic or chemopreventive agent.

Specification at p. 6, line 27-p. 7, line 7 (emphasis added). To be clear, the Applicant expressly included p16 and p27 within the definition of biological marker associated with senescence, apoptosis or terminal differentiation. *See* Specification at p. 7, line 8-11 ("[B]iological markers whose expression is induced or increases in cellular senescence, apoptosis and terminal differentiation may include but are not limited to p21, p27, p16, TGF-ß, IL-4, IL-6, and SA-ß-Gal, generally and collectively known as the senescence-like phenotype (SLP)"). With such express disclosure, there can be no question that there is written description support for claims 17-19. And, without explanation or support why one skilled in the art would understand that p16 and p27 are unique out of all of the disclosed biomarkers that they could not both be detected,

Applicant respectfully request withdrawal of this rejection and requests reconsideration of the claims.

Conclusion

In view of the above amendments and remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully Submitted,

Date: May 17, 2010

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